K 130043

FEB 1 2 2013

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8049
Fax: 919-433-4996

B. Contact Person

Natalie Smith
Regulatory Affairs Specialist

Lorraine DeLong
Manager RA/QE Surgical

C. Date Prepared
January 7, 2013

D. Device Name

Trade Name: Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System

Common Name: Autotransfusion Apparatus

Classification Name: Autotransfusion Apparatus

E. Device Description
The Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System is provided as a sterile unit intended for single patient use. The fluid path is non-pyrogenic. The Pleur-evac Sahara Plus System is used for the collection and continuous reinfusion of autologous blood. By attaching the Pleur-evac Sahara Autotransfusion Bag, the Pleur-evac Sahara Plus System serves as a bag reinfusion system. When autotransfusion is completed, the Pleur-evac Sahara Plus System can serve as a chest drainage collection unit.

F. Indications for Use

AUTOTRANSFUSION

1. For the collection of autologuous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post-operative situations

CHEST DRAINAGE

1. To evacuate air and/or fluid from the chest cavity or mediastinum
2. To help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum.
3. To help re-establish and maintain normal intra-thoracic pressure gradients.
4. To facilitate complete lung re-expansion to restore normal breathing dynamics.

The Pleur-evac® Autotransfusion Bag is indicated as a sterile, single use device used for collection and reinfusion of autologous blood from the thoracic cavity when attached to a Pleur-evac® System. The fluid path is non-pyrogenic.

G. Contraindications

Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System is contraindicated for:

- Pericardial, mediastinal, or systemic infections
- Pulmonary and respiratory infection or infestation
- Presence of malignant neoplasms
- Coagulopathies
- Suspected thoraco-abdominal injuries with possible enteric contamination
- Impaired renal function
- Intraoperative thoracic or mediastinal cavity use of topical thrombin, microfibrillar hemostatic agents or providine-iodine antiseptic gels or solutions and non I.V. compatible antibiotics

H. Substantial Equivalence

The proposed Pleur-evac® Plus Continuous Autotransfusion System is substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Pleur-evac® Autotransfusion Systems	Teleflex Medical, Inc.	K120953	December 10, 2012

I. Comparison To Predicate Devices

The proposed Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System has the same technology, indications for use and functional characteristics as

the predicate system. The proposed modification is a change in material to an indirect patient contacting component, which was driven by supplier obsolescence.

J. Materials

All patient contacting materials are in compliance with ISO10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion Systems and the predicate has been performed. The results of this comparison demonstrate that the Pleur-evac® High Negative Relief Valve filter is equivalent to the marketed predicate devices in performance characteristics.

L. Performance Data

The bench testing has been performed to verify that the performance of the proposed Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion Systems is substantially equivalent to the predicate device. The proposed filter material was validated according to test specifications and is summarized below.

Performance Data Results Summary		
Response Type	**Test Specification**	**Result**
Quantitative	Pressure Equalization Rate	**PASS** All values tested allowed the pressure in a full collection chamber to rise from 17 cm H_2O vacuum to 2 cm H_2O vacuum between 1 second and 22 seconds.
Qualitative (Pass, Fail)	Filter Position Visual	**PASS** All covers tested contacted the filter material on the entire cover retaining surface.
Qualitative (Pass, Fail)	Filter Visual	**PASS** All Pleur-evac units tested contained a filter in the HNRV assembly.
Quantitative	ASTM F1608-00(2009)	**PASS** All Pleur-evac units tested had an LRV > 4.

L. Conclusion

Based upon the comparative test results, the proposed Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System is substantially equivalent in performance to the predicate devices cleared to market via 510(k) K120953. The modification made to the proposed Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System does not introduce any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 12 2013

Teleflex Medical Incorporated
c/o Ms. Natalie Smith
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K130043
Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: January 22, 2013
Received: January 23, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130043

Device Name: Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System

Indications for Use:

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Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K130043